REMARKS

Applicants have reviewed and considered the Final Office Action dated October 28, 2008, and the cited references therein. In the Office Action, Claims 1-36 have been rejected under 35 U.S.C. § 103(a). In view of the amendments and the following remarks, Applicants request reconsideration and allowance of the pending claims.

Claim 24

Applicants initially point out that in the previous response, Claim 24 was amended with the added limitations underlined. See, Amendment filed Nov. 8, 2007, wherein Claim 24 was amended as follows:

> 24. A process for evaluating donor bone suitability for implant preparation comprising non-destructively assessing cortical thickness at one or more pre-selected sites of the donor bone.

However, the claim status identifier for Claim 24 was provided as "(Original)." Applicants clarify herein that the claim status identifier should have been "(Currently Amended)."

Rejections under 35 U.S.C. § 103(a)

Claims 1-23 and 30-36 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over White et al. (US 4,436,684) in view of Janas et al. (US 2001/0016353 A1). Applicants respectfully traverse the rejection for at least the following reasons.

Claim 1 is directed to a process for evaluating donor bone suitable for implant preparation. The process comprises, in part, "imaging a donor bone, prior to implantation, using a three-dimensional imaging scan at one or more sites of the bone."

Neither White et al. nor Janas et al., alone or in combination, teach or suggest "imaging a donor bone, prior to implantation, using a three-dimensional imaging scan at one or more sites of the bone." In contrast, White et al. disclose a method of constructing three dimensional corporeal models of structures internal to bodies. Col. 1, ll. 7-9. The method of White et al. commences with the operation of a computerized tomographic device to derive three

dimensional coordinate data defining a three dimensional representation of a selected structure internal to a patient. Col. 3, ll. 20-24. The coordinate data is provided in a format compatible with a machine-controlled sculpting tool device. Col. 3, ll. 28-31. A corporeal model of an internal bodily structure is then formed from a workpiece of suitable material by operating the machine controlled sculpting tool device in accordance with the coordinate data. Col. 3, ll. 31-38. The corporeal model is fabricated from suitable material selected according to the expected use of the model. Col. 5, ll. 26-28. Examples of suitable material for the model are Silastic and Proplast. Col. 5, ll. 28-30. Nowhere do White et al. disclose evaluating donor bone. More particularly, White et al. do not teach nor suggest "imaging a donor bone, prior to implantation, using a three-dimensional imaging scan at one or more sites of the bone," as recited in Claim 1. The Examiner agrees that "White et al. do not specifically teach the imaging of donor bone." Present Action, p. 3.

Janas et al. do not remedy the fundamental disclosure deficiencies of White et al. The disclosure of Janas et al. does not relate to donor bone, and thus does not relate to imaging a donor bone. Rather, Janas et al. disclose resorbable ceramic scaffolds for using in biological applications, and their method of production. Para. [0001]. Specifically, Janas et al. disclose scaffolds, formed via replication, or relic technique, and useful as biological replacements for hard tissue. Para. [0001]. The process comprises impregnating an organic fabric with a metal and phosphate ceramic precursor and heat treating the structure to decompose the organic fabric and any nitrates that may be present to form an unsintered biocompatible ceramic implant device. Para. [0024]. Janas et al. do not disclose evaluating donor bone suitable for implant preparation. More particularly, Janas et al. do not teach nor suggest "imaging a donor bone, prior to implantation, using a three-dimensional imaging scan at one or more sites of the bone," as recited in Claim 1.

In paragraph [0038], Janas et al. disclose the structure may be filled with resorbable synthetic polymers or biopolymers or ceramic materials that may or may not contain materials that promote bone growth through the device. These include autograft, allograft, or xenograft bone . . . Para. [0038]. Nonetheless, Janas et al. do not teach nor suggest evaluating donor bone, and particularly do not teach nor suggest a process for evaluating donor bone comprising

"imaging a donor bone, prior to implantation, using a three-dimensional imaging scan at one or more sites of the bone."

The Examiner asserts:

> Janas et al. teach a process comprising: imaging a donor bone using scanning (par. 0041) and wherein following the imaging process, parameters are evaluated to assess the suitability of the bone for implantation. Within the broadest reasonable interpretation of the claim language, Janas et al. is applicable as prior art since there is no indication that imaging is done prior to implanting of the bone. Present Action, p. 3.

However, paragraph [0041] of Janas et al. relates to using the ceramic scaffold for the engineering of bone tissue to facilitate bone healing. Particularly, Janas et al. discloses the structure would be placed in cell culture and the cells seeded onto or into the structure. Para. [0041]. The structure would be maintained in a sterile environment and then implanted into the donor patient once the cells have invaded the microstructure of the scaffold. Para. [0041]. Janas et al. disclose "[a]dditionally, radio-opaque markers may be added to the scaffold to allow imaging after implantation." Para. [0041]. Nonetheless, this statement does not rise to the level of disclosure required for teaching or suggesting "imaging a donor bone, prior to implantation, using a three-dimensional imaging scan at one or more sites of the bone," as recited in Applicants' Claim 1. Furthermore, in stark contrast to the Examiner's assertion, Janas et al. do not disclose that following the imaging process, parameters are evaluated to assess the suitability of the bone for implantation. At most, Janas et al. disclose the well-known use of radio-opaque markers for identifying implants after implantation.

Furthermore, as the Examiner agrees on page 3 of the present Action, Janas et al. do not disclose "imaging a donor bone, prior to implantation." Nonetheless, the Examiner asserts:

> [S]uch a modification would have been obvious to one of ordinary skill in the art at the time frame of invention in order to eliminate the need for removing the bone after imaging as indicated by Janas et al., if the implant is not suited. Present Action, p. 3.

However, Janas et al. nowhere disclose, teach, nor suggest "removing the bone after imaging . . . if the implant is not suited," as suggested by the Examiner. Particularly, Janas et al. do not teach

nor suggest evaluating donor bone, and more particularly do not teach nor suggest "imaging a donor bone, prior to implantation, using a three-dimensional imaging scan at one or more sites of the bone." As stated above, Janas et al. merely disclose the well-known use of radio-opaque markers for identifying implants after implantation. As such, the Examiner's asserted modification to the teachings of Janas et al. would not be obvious.

Therefore, Claim 1 is not made obvious by White et al. in view of Janas et al. Claims 2-13 and 30 depend from Claim 1 and are patentable for the same reasons as Claim 1 and for the additional limitations recited therein. For example, Claims 4 and 5 further illustrate that the imaging of a donor bone is done prior to implant. Specifically, Claim 4 recites "formulating an implant cutting plan after assessing the donor bone's suitability for fabrication into a given implant configuration based on the measured parameters," and Claim 5 recites "the donor bone is cut into implants based on the implant cutting plan." Thus, in the process of Claim 5, the implants are not cut until after formulating a cutting plan, which is further performed after assessing the donor bone. Neither White et al. nor Janas et al., alone or in combination, teach or suggest "formulating an implant cutting plan after assessing the donor bone's suitability for fabrication into a given implant configuration based on the measured parameters" or that "the donor bone is cut into implants based on the implant cutting plan." Reconsideration and withdrawal of the rejection are respectfully requested.

Claim 14 is directed to a process for evaluating donor bone suitability for implant preparation. The process comprises, in part, "imaging the donor bone, prior to implantation, using three-dimensional image scanning at one or more sites on the donor bone."

As stated above, neither White et al. nor Janas et al., alone or in combination, teach or suggest evaluating donor bone, and particularly do not teach nor suggest "imaging a donor bone, prior to implantation, using three-dimensional image scanning at one or more sites of the bone." Rather, White et al. disclose prostheses made of Silastic and Proplast, and Janas et al disclose resorbable ceramic scaffolds.

Therefore, Claim 14 is not made obvious by White et al. in view of Janas et al. Claims 15-23 and 31 depend from Claim 14 and are patentable for the same reasons as Claim 14 and for

the additional limitations recited therein. Reconsideration and withdrawal of the rejection are respectfully requested.

Claim 32 is directed to a method of formulating a bone implant cutting plan. The method comprises "assessing the three-dimensional morphometric measurements of a donor bone, prior to implantation, whereby said measurements specify data regarding the fabrication of a given implant configuration for the donor bone based on said measurements; wherein said cutting plan identifies cutting locations on said donor bone."

Neither White et al. nor Janas et al., alone or in combination, teach or suggest "assessing the three-dimensional morphometric measurements of a donor bone, prior to implantation, whereby said measurements specify data regarding the fabrication of a given implant configuration for the donor bone based on said measurements; wherein said cutting plan identifies cutting locations on said donor bone." Rather, White et al. disclose a corporeal model of an internal bodily structure is formed from a workpiece of suitable material by operating a machine controlled sculpting tool device in accordance with coordinate data. Col. 3, ll. 31-38. The corporeal model is fabricated from suitable material, such as Silastic and Proplast. Col. 5, ll. 26-30. Similarly, Janas et al. disclose resorbable ceramic scaffolds. Thus, neither White et al. nor Janas et al. teach or suggest measurements that specify "data regarding the fabrication of a given implant configuration for the donor bone based on said measurements" or "wherein said cutting plan identifies cutting locations on said donor bone."

Therefore, Claim 32 is not made obvious by White et al. in view of Janas et al. Claims 33, 35, and 36 depend from Claim 32 and are patentable for the same reasons as Claim 32 and for the additional limitations recited therein. Reconsideration and withdrawal of the rejection are respectfully requested.

Claims 24-29 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Uchiyama et al. (NPL – "A Morphometric Comparison of Trabecular Structure of Human Ilium Between Microcomputed Tomography and Conventional Histomorphometry") in view of Janas et al. Applicants respectfully traverse the rejection for at least the following reasons.

Claim 24 is directed to a process for evaluating donor bone suitability for implant preparation. The process comprises "non-destructively assessing cortical thickness at one or more pre-selected sites of the donor bone, prior to implantation."

Neither Uchiyama et al. nor Janas et al., alone or in combination, teach or suggest "non-destructively assessing cortical thickness at one or more pre-selected sites of the donor bone, prior to implantation." Rather, Uchiyama discloses a tool for imaging and nondestructively quantifying the microarchitecture of trabecular bone in unprocessed surgical bone biopsy specimens. Abstract. Such a tool is useful for treating patients with various metabolic bone diseases, such as osteoporosis. Pg. 493. Nowhere does Uchiyama disclose donor bone. More particularly, Uchiyama does not teach nor suggest "a process for evaluating donor bone suitability for implant preparation comprising non-destructively assessing cortical thickness at one or more pre-selected sites of the donor bone, prior to implantation," as recited in claim 24.

Janas et al. do not remedy the fundamental disclosure deficiencies of Uchiyama et al. As stated above, the disclosure of Janas et al. does not relate to donor bone, and thus does not relate to evaluating a donor bone. Rather, Janas et al. disclose resorbable ceramic scaffolds, formed via replication, or relic technique, and useful as biological replacements for hard tissue. Para. [0001]. While Janas et al. disclose "radio-opaque markers may be added to the scaffold to allow imaging after implantation," this statement does not rise to the level of disclosure required for teaching or suggesting evaluating donor bone, and certainly not to the level required for teaching or suggesting "non-destructively assessing cortical thickness at one or more pre-selected sites of the donor bone, prior to implantation," as recited in Applicants' Claim 24. At most, Janas et al. disclose the well-known use of radio-opaque markers for identifying implants after implantation.

Therefore, Claim 24 is not made obvious by Uchiyama et al. in view of Janas et al. Claims 25-29 depend from Claim 24 and are patentable for the same reasons as Claim 24 and for the additional limitations recited therein. Reconsideration and withdrawal of the rejection are respectfully requested.

Conclusion

This response is being submitted on or before April 28, 2008, with the appropriate fee for a 3-month extension of time, making this a timely response. It is believed that no additional fees are due in connection with this filing. However, the Commissioner is authorized to charge any additional fees, including extension fees or other relief which may be required, or credit any overpayment and notify us of same, to Deposit Account No. 04-1420.

This application now stands in allowable form and reconsideration and allowance is respectfully requested.

Respectfully submitted,

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